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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,272	04/06/2001	James M. Lipton	259/058	6351

34055 7590 05/22/2003

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EXAMINER
CHISM, BILLY D

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/828,272	LIPTON ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is in response to Paper No. 15, filed 04 March 2003. Applicants traversed the restriction requirement and provisionally elected SEQ ID NO: 1 and cortisone. The requirement was reconsidered and the Examiner restricted the claimed invention again. The Applicants argument regarding the separation of the anti-inflammatories was considered and is addressed accordingly in the groupings below. Applicants will also see that the classifications were righted and the reasons for restriction applied.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Set 1: (Groups I-IV),

I. Claims 1-4, 7-9, 20-23 and 26-28, drawn to a pharmaceutical composition comprising SEQ ID NO: 1 and an anti-inflammatory that is a glucocorticoid, classified in class 514, subclass 18.

II. Claims 1-4, 7-9, 20-23 and 26-28, drawn to a pharmaceutical composition comprising SEQ ID NO: 2 and an anti-inflammatory that is a glucocorticoid, classified in class 514, subclass 15.

III. Claims 1-4, 7-9, 20-23 and 26-28, drawn to a pharmaceutical composition comprising SEQ ID NO: 3 and an anti-inflammatory that is a glucocorticoid, classified in class 514, subclass 16.

IV. Claims 1-4, 7-9, 20-23 and 26-28, drawn to a pharmaceutical composition comprising SEQ ID NO: 4 and an anti-inflammatory that is a glucocorticoid, classified in class 514, subclass 14.

Groups I-IV differ in structure and in function. Therefore, the polypeptide products of Groups I-IV are patentably distinct. If any one of Groups I-IV is elected, then the elected invention will be examined only in-so-far as it pertains to the elected invention.

Set 2: (Groups V-VIII),

V. Claims 1-2, 5-9, 20-21 and 24-28, drawn to a pharmaceutical composition comprising SEQ ID NO: 1 and a non-steroidal anti-inflammatory drug, classified in class 514, subclass 18.

VI. Claims 1-2, 5-9, 20-21 and 24-28, drawn to a pharmaceutical composition comprising SEQ ID NO: 2 and a non-steroidal anti-inflammatory drug, classified in class 514, subclass 15.

VII. Claims 1-2, 5-9, 20-21 and 24-28, drawn to a pharmaceutical composition comprising SEQ ID NO: 3 and a non-steroidal anti-inflammatory drug, classified in class 514, subclass 16.

VIII. Claims 1-2, 5-9, 20-21 and 24-28, drawn to a pharmaceutical composition comprising SEQ ID NO: 4 and a non-steroidal anti-inflammatory drug, classified in class 514, subclass 14.

Groups V-VIII differ in structure and in function. Therefore, the polypeptide products of Groups V-VIII are patentably distinct. If any one of Groups V-VIII is elected, then the elected invention will be examined only in-so-far as it pertains to the elected invention.

Set 3: (Groups IX-XII),

IX. Claims 10-13, 16-19, 29-32 and 35-38, drawn to a method of treatment comprising administering a pharmaceutical composition comprising SEQ ID NO: 1 and a glucocorticoid anti-inflammatory drug, classified in class 514, subclass 18.

X. Claims 10-13, 16-19, 29-32 and 35-38, drawn to a method of treatment comprising administering a pharmaceutical composition comprising SEQ ID NO: 2 and a glucocorticoid anti-inflammatory drug, classified in class 514, subclass 15.

XI. Claims 10-13, 16-19, 29-32 and 35-38, drawn to a method of treatment comprising administering a pharmaceutical composition comprising SEQ ID NO:

3 and a glucocorticoid anti-inflammatory drug, classified in class 514, subclass 16.

XII. Claims 10-13, 16-19, 29-32 and 35-38, drawn to a method of treatment comprising administering a pharmaceutical composition comprising SEQ ID NO: 4 and a glucocorticoid anti-inflammatory drug, classified in class 514, subclass 14.

The methods of Groups IX-XII differ in product used to practice the method, as well as the detected polypeptide. Therefore, the methods of Groups IX-XII are patentably distinct. If any one of Groups IX-XII is elected, then the elected invention will be examined only in-so-far as it pertains to the elected invention.

Set 4: (Groups XIII-XVI),

XIII. Claims 10-11, 14-19, 29-30 and 33-38, drawn to a method of treatment comprising administering a pharmaceutical composition comprising SEQ ID NO: 1 and a non-steroidal anti-inflammatory drug, classified in class 514, subclass 18.

XIV. Claims 10-11, 14-19, 29-30 and 33-38, drawn to a method of treatment comprising administering a pharmaceutical composition comprising SEQ ID NO: 2 and a non-steroidal anti-inflammatory drug, classified in class 514, subclass 15.

XV. Claims 10-11, 14-19, 29-30 and 33-38, drawn to a method of treatment comprising administering a pharmaceutical composition comprising SEQ ID NO: 3 and a non-steroidal anti-inflammatory drug, classified in class 514, subclass 16.

XVI. Claims 10-11, 14-19, 29-30 and 33-38, drawn to a method of treatment comprising administering a pharmaceutical composition comprising SEQ ID NO: 4 and a non-steroidal anti-inflammatory drug, classified in class 514, subclass 14.

The methods of Groups XIII-XVI differ in product used to practice the method, as well as the detected polypeptide. Therefore, the methods of Groups XIII-XVI are patentably distinct. If any one of Groups XIII-XVI is elected, then the elected invention will be examined only in-so-far as it pertains to the elected invention.

The patentable distinctness between the Inventions within a Set of Inventions has been provided for each Set above. The patentable distinctness between the sets of inventions will be interpreted as follows.

The Sets of Inventions are independent and/or distinct, each from the other because of the following reasons:

The compositions of Set 1 and Set 2 are independent and/or distinct from each other since they are different in structure and function, and are capable of use in patentable distinct methods.

The methods of Set 3 and Set 4 are independent and/or distinct from each other since they are different methods requiring different ingredients.

The compositions of Sets 1-2 and the methods of Set 3-4 are independent and/or distinct inventions as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be use in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions of Sets 1-2 can be used for the treatment of arthritis.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism
21 May 2003

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600